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REMARKS

This is a full and timely response to the non-final Official Action mailed May 18, 2006.
Reconsideration of the application in light of the following remarks is respectfully requested.

Status of Claims:

Claims 1-23 are currently pending for further action. No amendments are made by the present paper.

Prior Art Issues--Anticipation:

The outstanding Office Action rejected claims 1-4, 7, 10-12, 14, 16, 17, 19 and 21-23 as anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 6,066,163 to John ("John"). For at least the following reasons, this rejection is still respectfully traversed.

Claim 1 recites:

In a neurostimulator implant system having multiple electrode contacts through which electrical stimuli are applied to tissue of a patient, and wherein an evoked compound action potential (ECAP) occurs in the tissue when an electrical stimulus of sufficient intensity has been applied to the tissue, and wherein the presence or absence of an ECAP in response to an applied stimulus serves as a useful objective indicator relative to the operation and functionality of the implant system, an improved method of eliciting an ECAP comprising the steps for:

- generating electrical stimuli with selectable degrees of intensity;
- delivering the electrical stimuli to at least two of the multiple electrode contacts, such that the at least two electrode contacts output an electrical current into the tissue, *the electrode contacts being arranged such that the electrical current output by the at least two electrode contacts combines to provokes a single ECAP in the tissue and,* while delivering the electrical stimuli, gradually adjusting the intensity of the electrical stimuli and monitoring for the occurrence of said single ECAP with another separate electrode contact of the multiple electrode contacts;

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noting the intensity of the applied electrical stimuli when the ECAP is first observed;

using the intensity of the electrical stimuli applied to the at least two electrode contacts that caused the ECAP to first occur as a guide to setting the intensity of the electrical stimuli of the neurostimulator implant system during operation of the neurostimulator implant system.
(emphasis added).

It should be noted that claim 1 recites at least two electrode contacts that are used together to output an electrical current that *combines* to produce a *single* occurrence of an evoked compound action potential (ECAP). Unfortunately, the recent Office Action utterly fails to take this subject matter into account and is, therefore, unresponsive to Applicant's previous amendment.

With regard to claim 1, the recent Office Action states that the "Examiner maintains the position that the John reference does teach of at least two electrode contacts (reference #s 76 and 78, and see col. 10 lines 7-14) that are capable of provoking evoked action potentials in a patient's tissue (col. 9 lines 51-52)." (Action of 5/18/06, p. 2). Regardless of whether this statement is accurate, it fails to indicate how or where John teaches at least two electrode contacts "*arranged such that the electrical current output by the at least two electrode contacts combines to provokes a single ECAP in the tissue*" as claimed.

The Office Action further states that the "Examiner interprets two electrodes (76 and 78) as being two electrode contacts, similarly [sic] to the electrode contacts as claimed by Applicant." (Action of 5/18/06, p. 2). Again, this statement fails to indicate how or where John teaches at least two electrode contacts "*arranged such that the electrical current output by the at least two electrode contacts combines to provokes a single ECAP in the tissue*" as claimed.

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It is incumbent upon the Examiner to identify where in the reference each element of a claim may be found. *Ex parte Levy*, 17 U.S.P.Q.2d 1461 (BPAI 1990). Consequently, when the Examiner fails to identify a claimed element, the Examiner has failed to establish a prima facie case of anticipation. For at least this reason, the rejection based on John should be reconsidered and withdrawn.

Moreover, one of skill in the art reading the John reference would clearly appreciate that John does not teach or suggest the subject matter of claim 1. Rather, John is merely representative of the prior art described in Applicant's specification. As stated in Applicant's specification, "[t]raditional methods used to elicit the electrically-evoked compound action potential, or ECAP, deliver stimulation to a single electrode contact. There are cases where such application of a stimulus to a single electrode contact do[es] not evoke a suitable action potential." (Applicant's specification, paragraph 0003). To improve on this situation, Applicant has discovered that by driving two or more electrodes, either simultaneously or in rapid succession, to output an electrical current, a single, specific instance of an ECAP can be more effectively and reliably evoked. (Applicant's specification, paragraph 0024).

In contrast, John teaches a direct brain stimulation system with electrodes dispersed over different portions of the brain. (See John, Fig. 1). John does not ever teach or suggest the claimed method in which at least two electrodes are used together with an electrical current that *combines* to produce a single occurrence of an ECAP. The Office Action fails to cite any portion of John which provides such a teaching. Rather, it appears that the Office Action is attempting to read subject matter into the John reference that is not actually there.

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Contrary to claim 1, John suggests that two electrodes (76 and 78) are located in different regions of the brain and presumably, therefore, would not be capable of working together to provide a single ECAP. According to John, with reference to John's Fig. 3, "stimulation set #1 76 contains at least 1 DBS device which stimulates a first brain region. Additionally, a second brain area is stimulated by stimulation set #2 78 which also contains at least 1 DBS device." (John, col. 10, lines 10-15).

Moreover, claim 1 also recites that the "at least two electrode contacts output an electrical current into the tissue, *while gradually adjusting the intensity* of the electrical stimuli and while monitoring for the occurrence of an ECAP with another separate electrode contact." John does not teach or suggest outputting an electrical current into tissue *while gradually adjusting the intensity* of the electrical stimuli and while also monitoring for the occurrence of an ECAP with another separate electrode contact. Remarkably, even though Applicant noted this subject matter in claim 1 on the record in a previous paper, the recent Office Action still fails to even address this subject matter of claim 1 and fails to indicate how or where such subject matter is taught by John.

Consequently, the recent Office Action fails to address the subject matter actually claimed. Specifically, the recent Office Action fails to indicate how or where John teaches at least two electrode contacts "*arranged such that the electrical current output by the at least two electrode contacts combines to provokes a single ECAP in the tissue*" as claimed. The recent Office Action further fails to indicate how or where John teaches or suggests "at least two electrode contacts output an electrical current into the tissue, *while gradually adjusting the*

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intensity of the electrical stimuli and while monitoring for the occurrence of an ECAP with another separate electrode contact.”

"A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). See M.P.E.P. § 2131. For at least these reasons, the rejection of claim 1 and its dependent claims based on John should be reconsidered and withdrawn.

Similarly, independent claim 10 recites:

In a neurostimulator implant system having multiple spaced-apart electrode contacts and means for delivering electrical stimuli through selected ones of the multiple electrode contacts for the purpose of stimulating tissue of a patient, an improved neurostimulator implant system adapted to elicit an evoked compound action potential (ECAP) from the tissue of the patient when an electrical stimulus of sufficient intensity is applied to the tissue, comprising:

- means for generating electrical stimuli with selectable degrees of intensity;
- means for delivering the electrical stimuli to at least two of the multiple electrode contacts, such that the at least two electrode contacts output an electrical current into the tissue, while gradually adjusting the intensity of the electrical stimuli, *the electrode contacts being arranged such that the electrical current output by the at least two electrode contacts combines to provokes a single ECAP in the tissue;*

- means for monitoring another separate electrode contact of the multiple electrode contacts for the occurrence of said single ECAP, said separate electrode contact that is monitored being located near the at least two multiple electrode contacts to which the electrical stimuli is delivered;

- means for noting the intensity of the applied electrical stimuli when the ECAP is first observed; and

- means for using the intensity of the electrical stimuli applied to the at least two electrode contacts that caused the ECAP to first occur as a guide to setting the intensity of the electrical stimuli of the neurostimulator implant system during operation of the neurostimulator implant system.

(emphasis added).

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As demonstrated above, John fails to teach or suggest the claimed “means for delivering the electrical stimuli to at least two of the multiple electrode contacts, *the electrode contacts being arranged such that the electrical current output by the at least two electrode contacts combines to provokes a single ECAP in the tissue.* (emphasis added). Additionally, John fails to teach or suggest “gradually adjusting the intensity of the electrical stimuli” in connection with “means for monitoring another separate electrode contact of the multiple electrode contacts for the occurrence of an ECAP.

Moreover, the recent Office Action utterly fails to address this subject matter in claim 10. For at least these reasons, the rejection of claim 10 and its dependent claims based on John should also be reconsidered and withdrawn.

Independent claim 16 recites:

A cochlear implant system comprising:
means for applying a stimulus pulse to at least two electrodes of multiple electrodes, either simultaneously or sequentially at a fast rate, said at least two electrodes outputting an electric current into patient tissue in order elicit an objectively-determinable response indicative of appropriate stimulation levels for the system, *the electrodes being arranged such that the electrical current output by the at least two electrodes combines to provokes a single objectively-determinable response;* and
means for detecting said objectively-determinable response.
(emphasis added).

John fails to teach or suggest a “cochlear implant system.” On this point, the recent Office Action argues that “John also teaches of the implantable system and method as being capable of functioning as an auditory prosthesis (col. 14, lines 63-67).” (Action of 5/18, p. 3) (emphasis added). This is a clear misstatement of what John actually teaches. John does not teach or suggest that the described brain stimulator and method are capable of functioning as an

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auditory prosthesis. Rather, John teaches that the disclosed brain stimulator and method can be used *with* a separate auditory prosthesis. According to John,

Additionally, the ABS system and method of the present invention can be used in the treatment of sensory disorders by sensory aids that stimulate the CNS or sensory pathway, such as a multi-channel implantable neural stimulator which functions as an auditory prosthesis. By comparing the present EP to a sensor input to a reference EP obtained from a past sensor input the stimulation parameters of an implanted device can be set to achieve the optimum performance from the implanted stimulator. (John, col. 14, line 63-col. 15, line 4).

Consequently, John does not teach or suggest a device or methods that can be used as a cochlear implant system, but rather merely teaches a brain stimulator that may be used to help set the stimulation parameters to optimize the performance of such a system.

Thus, John does not teach or suggest a cochlear implant system as claimed. For at least this reason, the rejection of claim 16 and its dependent claims based on John should be reconsidered and withdrawn.

Moreover, as demonstrated above, John fails to teach or suggest a system that comprises means for applying a stimulus pulse with at least two electrodes outputting an electric current that *combines* to provoke a single, objectively-determinable response indicative of appropriate stimulation levels for the system. For at least this reason, the rejection of claim 16 and its dependent claims based on John should be reconsidered and withdrawn.

"A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). See M.P.E.P. § 2131. Consequently, for at least these reasons, the

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rejection of claim 16 and its dependent claims based on John should also be reconsidered and withdrawn.

Independent claim 21 recites:

An implantable stimulator system for stimulating tissue, said stimulator system comprising:

a plurality of electrodes each of which is configured to selectively output an electrical current to the tissue, wherein the system is configured to output an electrical current with two or more of the plurality of electrodes, simultaneously or in rapid succession, *wherein the current output by the two or more electrodes acts together on the tissue so as to evoke a single neural response;*

an electrode for detecting the neural response caused by the electrical current output by the two or more electrodes;

wherein detection of said single neural response is used by said system along with parameters defining said electrical current that evoked said neural response to determine initial stimulation parameters for said implantable stimulator.

(emphasis added).

As demonstrated amply above, John fails to teach or suggest a system with a plurality of electrodes "configured to output an electrical current with two or more of the plurality of electrodes, simultaneously or in rapid succession, *wherein the current output by the two or more electrodes acts together on the tissue so as to evoke a single neural response.*" (emphasis added).

John also fails to teach or suggest that "detection of said single neural response is used by said system along with parameters defining said electrical current that evoked said neural response to determine initial stimulation parameters for said implantable stimulator."

"A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). See M.P.E.P. § 2131. Consequently, for at least these reasons, the

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rejection of claim 21 and its dependent claims based on John should also be reconsidered and withdrawn.

Prior Art Issues—Obviousness:

Dependent claims 5, 6, 8, 9, 13, 15, 18 and 20 were rejected as being unpatentable under 35 U.S.C. § 103(a) over the combined teachings of John (cited above) and U.S. Patent No. 6,175,767 to Doyle (“Doyle”). This rejection is respectfully traversed for at least the following reasons.

The final Office Action states that “John and Doyle both teach of multichannel implantable hearing devices, and thus teach of analogous arts.” (Action of 11/30/05, p. 3). *This is clearly incorrect.*

As noted above, the teachings of John are related to direct brain stimulation “for the treatment of traumatic brain injury and the often resulting persistent vegetative state or ‘coma’ or the treatment of other brain dysfunctions such as movement disorders.” (John, col. 1, lines 8-11). John mentions that his system may be used in conjunction with an auditory prosthesis to optimize the operation of the auditory prosthesis. (John, col. 14, line 63-col. 15, line 4). However, John does not teach or suggest that the subject matter taught with regard to the disclosed method and system for brain stimulation can or should be incorporated into an auditory prosthesis.

Consequently, one of skill in the art considering the John and Doyle references might be inclined to use them as separate and complementary systems, but would have had no motivation whatsoever to incorporate the brain stimulation method and hardware taught by John into the

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inner ear stimulation taught by Doyle. Moreover, the final Office Action has failed to explain how or why one of skill in the art would have been motivated to attempt to combine the teachings of Doyle's implantable hearing device with John's direct brain stimulator.

"Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed Cir. 1992)." M.P.E.P. § 2143.01 (emphasis added). For at least this additional reason, the rejection of claims 5, 6, 8, 9, 13, 15, 18 and 20, based on the erroneous combination of John and Doyle, should be reconsidered and withdrawn.

Double Patenting;

Lastly, the recent Office Action provisionally rejected claims 1-20 based on the judicially-created doctrine of obviousness-type double patenting in view of claims 1-6 of co-pending Application No. 10/698,098. As this is merely a *provisional* rejection, Applicant takes no position at this time as to the relationship, if any, between the present claims and the claims of Application No. 10/698,098.

If co-pending Application No. 10/698,098 should be issued prior to the present application, Applicant will consider filing a terminal disclaimer to address the double patenting issue. However, Applicant need take no position at this time as to whether the claims of the

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present application and those of co-pending Application No. 10/698,098 might, at some future time, present an actual double patenting issue.

Conclusion:

For the foregoing reasons, the present application is thought to be clearly in condition for allowance. Accordingly, favorable reconsideration of the application in light of these remarks is courteously solicited. If any fees are owed in connection with this paper that have not been elsewhere authorized, authorization is hereby given to charge those fees to Deposit Account 18-0013 in the name of Rader, Fishman & Grauer PLLC. If the Examiner has any comments or suggestions which could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the number listed below.

Respectfully submitted,

DATE: August 9, 2006

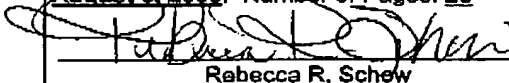


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